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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOROMA, BARBA M	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,612	BONELLO ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-35* is/are pending in the application.

4a) Of the above claim(s) *27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/01/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence SEQ ID No. 2*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 17-26 and 36-39, and SEQ ID No. 2, in the paper filed February 22, 2005, is hereby acknowledged.

Claims 17-26 are examined in this Application. Claims 1-16, and 36-45 are cancelled, and claims 27-35 are withdrawn as belonging to non elected inventions.

Response to Traversal on Election of sequence

Applicant traversed the restriction requirement because the criteria applied based on PCT Rule 13.1 in page 2 of the Office Action is improper as a matter of Law, indicating that the cited national criteria may not be applied in the present application. Applicant added further that in accordance with Article 27, paragraph 1 of the PCT, it is not permissible for a national Office to require compliance with requirements that are different from or in addition to the rules of the PCT and regulations thereof. Applicant maintained that the inventions listed as Groups I and II by the office Action relate to a single general inventive concept in agreement with PCT Rule 13.1. Applicant stated further that According to PCT Rule 13.2, a single inventive concept exists between the inventions of the claims when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features that define a contribution, which each of the claimed inventions, considered as a whole, makes over the prior art.

Applicant believes that the special technical feature of the instant invention is a promoter nucleotide sequence which comprises SEQ ID No. 2, or a sequence at least 80% identical to SEQ ID No. 2, which allows an expression of genes both specific to the interface between the embryo and the endosperm, and intervening early during the development of the endosperm. Consequently, Applicant believes that amended claims 17-19, 21-35, i.e, the promoter, an expression cassette, or a vector containing it, or a plant transformed with such a vector, constitute a single invention.

Applicants arguments in favor of a rejoinder of groups have been considered and not found convincing because claim 27, included in the group of claims 21-35 as stated, is not limited to SEQ ID No. 2, rather broadly claims any promoter nucleotide sequence. Accordingly, the promoter of claim 27 does not have to be the promoter sequence of SEQ ID No. 2, as argued by Applicant. Thus, the restriction requirement between groups I and II is hereby maintained and made Final.

Information Disclosure Statement

Applicant IDS is objected for failure to supply dates of publication on some documents. See uninitialled areas in attached IDS.

Claim Objection

12. Claims 17, 23, and 26, are objected for reciting "bound." Inserting --operatively-- in front of the word "bound" will overcome this objection.

Claim Rejection 35 USC 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24, line 7 recites the limitation "the fatty acids." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17, 18, 19, 21, and 22, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co.,

119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that:

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The claims are broadly drawn to an isolated promoter nucleotide sequence allowing an expression of the coding sequence to which it is bound, wherein said promoter comprises SEQ ID No. 2, or a sequence at least 80% identical to SEQ ID No. 2

The specification describes the cloning Esr2 promoter identified as SEQ ID No. 2 (page 19, lines 5-8, example 3). In example 4, page 22, lines 4-6, the specification describes fusion of the Hind-XbaI of the pEsr2 promoter with the coding sequence for GFP.

There is lack of written description in the specification regarding all possible polynucleotides comprising SEQ ID No. 2 or which are at least 80% identical to SEQ ID No. 2.

The specification fails to provide adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, the sequence of all possible polynucleotides comprising SEQ ID No. 2, or sequences that are at least 80% identical to SEQ ID No. 2, would be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 18, 19, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID No. 2, does not reasonably provide enablement for any promoter sequence that is at least 80% identical to SEQ ID No.2. The specification does not enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. The factors to be considered are as follows: Lack of guidance, State of the prior art, Nature of the invention, Unpredictability of the art, and Quantity of experimentation necessary.

Breadth of the claims: The claims are broadly drawn to an isolated promoter nucleotide sequence allowing an expression of the coding sequences to which it is bound, wherein said promoter sequence comprises SEQ ID No. 2 or a sequence at least 80% identical to SEQ ID No. 2.

Guidance of the specification: The specification describes the cloning Esr2 promoter identified as SEQ ID No. 2 (page 19, lines 5-8, example 3). In example 4, page 22, lines 4-6, the specification describes fusion of the Hind-XbaI of the pEsr2 promoter with the coding sequence for GFP.

The specification does not teach any and all polynucleotides comprising SEQ ID No. 2, or sequences that are at least 80% identical to SEQ ID No. 2.

State of the prior art: Polynucleotides comprising SEQ ID No. 2, or sequences that are at least 80% identical to SEQ ID No. 2 that are promoters specific to the region of the endosperm surrounding the embryo, is not taught in the prior art.

Nature of the invention: One skilled in the art would not know how to make and use isolated promoter nucleotides that comprise SEQ ID No. 2, or are at least 80% identical to SEQ ID No. 2 specific to the endosperm surrounding the embryo.

Unpredictability of the art: Guidance for making and using the claimed invention is necessary for enablement because of the teaching of Kim et al (Plant Mol Biol. 1994. 24, pages 105-117) that a twenty nucleotide sequence region is essential for the *nos* promoter to function (Abstract; results: page 109, right column, second paragraph). This finding shows that any change or substitution to a promoter sequence can result in altered activity and therefore an unpredictable outcome in promoter function and activity, in vivo.

Quantity of experimentation necessary: Undue trial and error experimentation would be required to isolate and screen through thousands of sequences that comprise SEQ ID No. 2, or that contain at least 805 of SEQ ID No. 2 that exhibit promoter activity.

Given the breadth of the claims encompassing all nucleic acid sequences that comprise SEQ ID No.2, or that are at least 80% identical to SEQ ID No.2, that retain promoter activity, the lack of guidance of the specification as discussed above, it would require undue experimentation to make and use the invention as claimed. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim Rejection 35 USC 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24, and 26, are rejected under 35 U.S.C. 102(b) as being anticipated by Czako et al (Mol Gen Genet 1992. Vol. 235, pages 33-40).

The claims are broadly drawn to an expression cassette comprising a promoter nucleotide sequence operatively bound to and allowing expression of a coding sequence in an embryo.

Czako et al anticipates all essential elements and limitations of this claim by teaching a pea vicilin promoter was fused to the coding region of the ditheria toxin A (DTx-A) chain gene, and introduced into Arabidopsis and tobacco plants (see Abstract; especially results and discussion, page 35, left column; page 36, bridging paragraph and entire right column).

Claim Rejection – 35 USC 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-19, 21-26, are rejected under 35 U.S.C. 103(a) as being unpatentable over Czako et al (Mol Gen Genet 1992. Vol. 235, pages 33-40), in view of Gunn et al (The plant Journal. 1997. Vol 12(1), pages 235-246

The claims are broadly drawn to The claims are broadly drawn to an isolated promoter nucleotide sequence allowing an expression of the coding sequences to which it is bound, wherein said promoter sequence comprises SEQ ID No. 2 or a sequence at least 80% identical to SEQ ID No. 2, and an expression cassette comprising a promoter nucleotide sequence operatively bound to and allowing expression of a coding sequence in an embryo.

Czako et al teach transformation of Arabidopsis and tobacco involving a promoter operably linked to a toxin gene expressed in the embryo (see Abstract; especially results and discussion, page 35, left column; page 36, bridging paragraph and entire right column).

Czako et al does not teach an endosperm-specific promoter expressed in a restricted region around the maize embryo.

Gunn et al teach the expression of ZmEsr gene, an endosperm-specific gene expressed in a restricted region around the maize embryo (Abstract; results, pages 237-242; discussion, page 242-245).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, to utilize the method of a promoter-gene fusion in an expression vector in an embryo, taught by Czako et al, and to modify that method by incorporating a promoter-gene fusion specific to the region around the endosperm in the embryo of a plant, as taught by Gunn et al.

Conclusion

7. No claims are found allowable. SEQ ID No. 2 is free of the art.

Contact Information

12. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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